

K110648

AUG 29 2011

**510(k) Summary**

**510(K) Owner:** Nova Biomedical Corporation  
**Registration Number:** 1219029  
**Address:** 200 Prospect St.  
 Waltham, MA 02454  
**Phone:** 781-894-0800  
**Fax Number:** 784-891-4806  
**Contact Person:** Paul W. MacDonald  
**Date Prepared:** 08/24/2011

**Proprietary Name:** Nova Stat Profile pHox Ultra Analyzer System

**Common or Usual Name:** Blood Gas/Electrolyte/Metabolite/CO-Oximetry Analyzer

**Classification Name:** Multiple

Classification Names:	Class No.	Reg. No.	Class
Blood Gases and Blood pH system	75CHL	862.1120	II
Sodium Test System	75JGS	862.1665	II
Potassium Test System	75CEM	862.1600	II
Calcium Test System	75JFP	862.1145	II
Chloride Test System	75CGZ	862.1170	II
Creatinine Test System	75CGL	862.1225	II
Magnesium Test System	75CFA	862.1495	I
Glucose Test System	75CGA	862.1345	II
Lactic Acid Test System	75KHP	862.1450	I
Urea Nitrogen System	75CDS	862.1770	II
Oxygen Saturation (SO2%)	91JKS	862.3220	I
Hematocrit Measuring Device	81JPI	864.6400	II
Hemoglobin System	81GKR	864.5620	II
Oxyhemoglobin	91JKS	862.3220	I
Carboxyhemoglobin	81GHS	864.7425	II
Methemoglobin	81JBJ	864.7360	II
Hemoglobin Standards and Controls	81JPK	864.8625	II
Hemoglobin Calibrator	81KRZ	864.8165	II
Calibrators	75JIX	862.1150	II
Quality Control Materials	81JJS	862.1660	I

**Product Codes:** CHL, JGS, CEM, JFP, CGZ, CGL, CFA, CGA, KHP, CDS, JKS, GHS, JPI, GKR, JKS, JBJ, JPK, KRZ, JIX, JJS

**Predicate Device:** Nova Stat Profile Critical Care Xpress (CCX), Model 1+ Analyzer System (K061830)

### Device Description:

As in the Nova Stat Profile Critical Care Xpress (CCX), Model 1+ Analyzer System (K061830) predicate device, the Nova Stat Profile pHox Ultra Analyzer System combines Blood Gas/pH, Chemistry, bilirubin and CO-Oximetry testing into one Point-of-Care Analyzer. This device is analyte configurable by the end user, based on tests needed.

As with the predicate, this device is microprocessor-based and incorporates:

- traditional electrode technology to measure blood pH, pCO<sub>2</sub>, pO<sub>2</sub>
- Nova Biomedical proprietary optical reflectance technology for the measurement of oxygen saturation
- ion selective electrode technology to measure blood sodium, potassium, chloride, ionized calcium, ionized magnesium
- enzyme/amperometric technology for glucose, urea nitrogen, lactate and creatinine measurements
- conductivity/Na<sup>+</sup> correction for hematocrit
- multi-wavelength reflectance/conductivity correction for hemoglobin.

Calibration standards with dissolved gases are provided in sealed pouches eliminating the need for users to calibrate the blood gas electrodes using external compressed gas cylinders. Quality control materials are available as external ampules and as internal auto-cartridge quality control packs. Sampling, calibration and quality control are fully automated.

Nova will market the Nova Stat Profile pHox Ultra Analyzer System in two configurations. The proposed Nova Stat Profile pHox Ultra Analyzer System with CO-Ox module (Catalog #42013) will be offered with all the parameters listed above. A second configuration will be offered, called the Nova Stat Profile pHox Ultra Analyzer System without the CO-Ox module (Catalog #42014). This configuration will not have the capability to measure Oxyhemoglobin (O<sub>2</sub>Hb), Carboxyhemoglobin (COHb), Methemoglobin (MetHb), and Reduced Hemoglobin (HHb) or bilirubin.

### Summary of the Technological Characteristics:

The Nova Stat Profile pHox Ultra Analyzer System is identical to the previously cleared for market Nova Stat Profile Critical Care Xpress (CCX), Model 1+ Analyzer System in intended use. Modifications were made necessary due to the obsolescence and availability of certain components and hardware, which required minor modifications to the device software to support these changes. The software algorithms used in performing the analysis of samples are unchanged from the predicate device. Minor modifications have been made to simplify the User Interface. The same reagents, calibrators, and controls are used for all of the analytes. The comparison table below compares the Nova Stat Profile pHox Ultra Analyzer System to the predicate Nova Stat Profile Critical Care Xpress (CCX), Model 1+ Analyzer System.

The results of software validation and performance verification testing confirmed that the modifications made to the hardware and software of the Nova Stat Profile pHox Ultra Analyzer System did not affect the safety, efficacy or performance of the system and the system is substantially equivalent to the predicate device.

**Comparison Table**

Characteristic	Predicate Stat Profile Critical Care Xpress with COOX Analyzer System	Proposed Stat Profile pHox Ultra with COOX Analyzer System
Intended Use	<p>The Stat Profile Critical Care Xpress (STP CCX) Analyzer with CO-Oximeter is intended for <i>in vitro</i> diagnostic use by health care professionals and for point-of-care usage in the quantitative determination of pH, PCO<sub>2</sub>, PO<sub>2</sub>, SO<sub>2</sub>%, Hematocrit (Hct), total Hemoglobin (tHb), Oxyhemoglobin (O<sub>2</sub>Hb), Carboxyhemoglobin (COHb), Methemoglobin (MetHb), Deoxyhemoglobin (HHb), and total bilirubin (tBil) in heparinized whole blood; Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>++</sup>, Mg<sup>++</sup>, Glucose (Glu), Lactate (Lac), BUN (Urea), and Creatinine (Creat) in heparinized whole blood, serum, or plasma. Total Bilirubin (tBil) was not evaluated on neonatal</p> <p>The STP CCX Analyzer without CO-Oximeter is intended for <i>in vitro</i> diagnostic use by health care professionals and/or point-of-care usage in the quantitative determination of pH, PCO<sub>2</sub>, PO<sub>2</sub>, SO<sub>2</sub>%, Hematocrit (Hct), Hemoglobin (Hb) in heparinized whole blood; Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>++</sup>, Mg<sup>++</sup>, Glucose (Glu), Lactate (Lac), BUN (Urea), and Creatinine (Creat) in heparinized whole blood, serum, or plasma samples.</p> <p>The intended use of the Nova STP CCX CO-Oximeter Calibrator Cartridge with Bilirubin and Deproteinizing Solution is for the quantitative determination of total Hemoglobin (tHb), Oxyhemoglobin (O<sub>2</sub>Hb), Carboxyhemoglobin (COHb), Methemoglobin (MetHb), Deoxyhemoglobin (HHb), and total bilirubin (tBil) in human blood using the STP CCX Analyzer with CO-Oximeter.</p> <p>Nova STP CCX CO-Oximeter Controls and Autocartridge QC are intended for <i>in vitro</i> diagnostic use by healthcare professionals for monitoring the performance of Nova STP CCX Analyzers.</p>	<p>The Stat Profile pHox Ultra Analyzer with CO-Oximeter is intended for <i>in vitro</i> diagnostic use by health care professionals and for point-of-care usage in the quantitative determination of pH, PCO<sub>2</sub>, PO<sub>2</sub>, SO<sub>2</sub>%, Hematocrit (Hct), total Hemoglobin (tHb), Oxyhemoglobin (O<sub>2</sub>Hb), Carboxyhemoglobin (COHb), Methemoglobin (MetHb), Deoxyhemoglobin (HHb), and total bilirubin (tBil) in heparinized whole blood; Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>++</sup>, Mg<sup>++</sup>, Glucose (Glu), Lactate (Lac), BUN (Urea), and Creatinine (Creat) in heparinized whole blood, serum, or plasma. Total Bilirubin (tBil) was not evaluated on neonatal samples.</p> <p>The Stat Profile pHox Ultra Analyzer without CO-Oximeter is intended for <i>in vitro</i> diagnostic use by health care professionals and/or point-of-care usage in the quantitative determination of pH, PCO<sub>2</sub>, PO<sub>2</sub>, SO<sub>2</sub>%, Hematocrit (Hct), Hemoglobin (Hb) in heparinized whole blood; Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>++</sup>, Mg<sup>++</sup>, Glucose (Glu), Lactate (Lac), BUN (Urea), and Creatinine (Creat) in heparinized whole blood, serum, or plasma.</p> <p>The intended use of the Nova STP pHox Ultra Calibrator Cartridge is for the quantitative determination of pH, PCO<sub>2</sub>, PO<sub>2</sub>, SO<sub>2</sub>%, Hematocrit (Hct), Hemoglobin (Hb) in heparinized whole blood; Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>++</sup>, Mg<sup>++</sup>, Glucose (Glu), Lactate (Lac), BUN (Urea), and Creatinine (Creat) in heparinized whole blood, serum, or plasma.</p> <p>The intended use of the Nova STP pHox Ultra/CCX CO-Oximeter Calibrator Cartridge with Bilirubin and Deproteinizing Solution is for the quantitative determination of total Hemoglobin (tHb), Oxyhemoglobin (O<sub>2</sub>Hb), Carboxyhemoglobin (COHb), Methemoglobin (MetHb), Deoxyhemoglobin (HHb), and total bilirubin (tBil) in human blood using STP pHox Ultra/CCX Analyzers with CO-Oximeter.</p> <p>Nova STP pHox Ultra/CCX ABG and CO-Oximeter Controls and Autocartridge QC are intended for <i>in vitro</i> diagnostic use by healthcare professionals for monitoring the performance of Nova STP pHox Ultra/CCX Analyzers.</p>
Analyzer	<p>Nova Stat Profile Critical Care Xpress (CCX), Model 1+ Analyzer System with CO-OX - 37413</p> <p>Nova Stat Profile Critical Care Xpress (CCX), Model 1+ Analyzer System - 35942</p>	<p>Nova Stat Profile pHox Ultra Analyzer System with CO-OX - 42013</p> <p>Nova Stat Profile pHox Ultra Analyzer System - 42014</p>
Consumables		
Calibrators	ABG, SO <sub>2</sub> , CO-Ox	Same
Controls	ABG Gas, ABG Chem, CO-Ox, External Lin Standards	Same
Sensors	PH, PCO <sub>2</sub> , PO <sub>2</sub> , SO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Cl <sup>-</sup> , Ca <sup>++</sup> , Mg <sup>++</sup> , Glu, Lac, Creat, BUN, REF	Same
Membranes	Glu Lac Creat BUN PCO <sub>2</sub> PO <sub>2</sub>	Same

Characteristic	Predicate Stat Profile Critical Care Xpress with COOX Analyzer System	Proposed Stat Profile pHox Ultra with COOX Analyzer System
Pump Tubing	ABG, CO-Ox	Same
Acceptable Samples	Syringe, Capillary	Same
Sample Volumes		
ABG Only	150µL	Same
CO-Ox Only	100µL	Same
Combined Analysis	210µL	Same
Micro Sample Volumes		
Full	120µL	Same
ABG	60µL	Same
ABG Plus	70µL	Same
ABG Nano	70µL	Same
Sensor Slope Limits		
pH	8.7 - 11.6	Same
PCO2	7.9 - 12.6	Same
PO2	15.0 - (-1.6)	Same
SO2	8.0 - 18.0	Same
Hct	14.0 - 45.0	Same
Hb	40.0 - 98.0	Same
Na+	8.8 - 11.0	Same
K+	8.3 - 12.1	Same
Cl-	7.7 - 13.2	Same
Ca++	8.3 - 12.6	Same
Mg++	9.5 - 15.0	Same
Glu	5.0 - 60.0	Same
Lac	6.0 - 100.0	Same
Creat	3.0 - 25.0	Same
BUN	9.3 - 13.5	Same
Principles of Measurement		
pH	Hydrogen ion-selective glass sensor	Same
PCO2	Severinghaus-type sensor	Same
PO2	Polarographic Clark-type sensor	Same
SO2	Reflectance photometry (fiber optics)	Same
Hct	Impedance sensor	Same
Hb	Impedance sensor	Same
Na+	Sodium ion-selective glass sensor	Same
K+	Potassium ion-selective sensor	Same
Cl-	Chloride ion-selective sensor	Same
Ca++	Calcium ion-selective sensor	Same
Mg++	Magnesium ion-selective sensor	Same
Glu	Enzymatic sensor	Same
Lac	Enzymatic sensor	Same
Creat	Enzymatic sensor	Same
BUN	Enzymatic sensor	Same
THb	Spectrophotometric	Same
O2Hb	Spectrophotometric	Same
COHb	Spectrophotometric	Same
MetHb	Spectrophotometric	Same
TBil	Spectrophotometric	Same
Design		
Touch Screen	10.4" LCD, 640x480 pixel, Resistive Touch	12.1" LCD, 1024x768 pixel, Resistive Touch
Menu	Fully configurable test menu based on above sensors	Test menu has not changed.
Printer	4.25" Roll, Thermal Transfer	2" Roll, Thermal Transfer
Sampler	Two Motor, 4 DOF, Ø and Z axis	Single Motor, Fixed Path Ø and Z axis

Characteristic	Predicate Stat Profile Critical Care Xpress with COOX Analyzer System	Proposed Stat Profile pHox Ultra with COOX Analyzer System
Chassis	Molded GF PC Base w/ Aluminum Welded Frame and Molded ABS/PC Cover.	Aluminum Riveted and Welded Base and Frame w/ Aluminum Cover
ABG System		
ABG Sensor Module	Combined Flow-through/Flow-by w/ optical SO <sub>2</sub>	Same
ABG Probe/S-Line	Stainless Probe w/ Polyurethane and Saran flexible tubing, In-Line Air detector	No Polyurethane used, shorter stainless steel portion dictated use of less gas permeable material.
ABG Pump	Peristaltic Pump w/ Pressure Plate, TPE Tubing (Pharmed BPT)	Same
Reagent Valves	Ceramic Shear Valves	Same
Other Valves	Pinch Style, Extruded TPE and Molded Silicone Tubing	Same
CO-Ox System		
CO-Ox Probe/S-Line	Stainless Probe w/ Polyurethane and Saran flexible tubing, In-Line Air detector	No Polyurethane used, shorter stainless steel portion dictated use of less gas permeable material.
CO-Ox Pump	Peristaltic Pump w/o Pressure Plate, Molded Silicone Tubing (Q7-4840)	Peristaltic Pump w/ Pressure Plate, Extruded TPE Tubing (Pharmed BPT)
Reagent Valves	Ceramic Shear Valves	Same
Spectrophotometer	Broad Spectrum Spectrometer	Same
Lamp House	Krypton Calibration Lamp / LED Light Source	Same
Cuvette Slide Assembly	Machined aluminum pre-heated slide w/ acrylic and sapphire cuvette assembly	Cast aluminum pre-heated slide w/ acrylic and sapphire cuvette assembly
Analog Board	precision low level analog front end w/ amperometric and potentiometric amplifiers, air detector circuitry and temperature control circuitry	Same
Deproteinizing Algorithm	"bleach type" agent can be scheduled to run through COOX branch for regular deproteinization	Same process, but spectrophotometer compares cuvette absorbance before and after sample, and schedules immediate deproteinization if difference is detected.
CoHb algorithm	Multi-wavelength Linear Regression Chemometrics	Same
tBil algorithm	Multi-wavelength Linear Regression Chemometrics	Same
Hemolyzer	Chemically Lysed with mechanical mixing	Same
Software/HW Architecture		
Graphical User Interface (GUI)	CCX user interface	Interface updated and tested as part of software validation. Functionality is equivalent to the predicate.
Storage media	IDE Hard Drive	SATA Hard Drive
Operating System	Windows 2000 Embedded	Windows 7 Embedded
Host Computer	Ibase IB880	Axiomtek 84831



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Nova Biomedical Corporation  
c/o Paul W. MacDonald  
200 Prospect St.  
Waltham, MA 02454

Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

AUG 29 2011

Re: k110648

Trade/Device Name: Nova Stat Profile pHox Ultra Analyzer System with CO-OX

Regulation Number: 21 CFR 862.1120

Regulation Name: Blood gases (pCO<sub>2</sub>, pO<sub>2</sub>) and blood pH test system

Regulatory Class: Class II

Product Code: CHL, JGS, CEM, CGZ, JFP, CFA, NGD, CDS, CGL, GGZ, GLY, GKK,  
GHS, GJC, JJB, CGA, BXX, JIX

Dated: 2 August 2011

Received: 4 August 2011

Dear Dr. MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

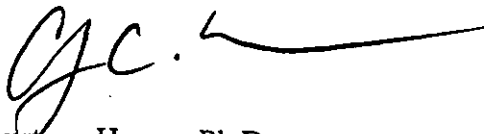
If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CHC', followed by a long horizontal line extending to the right.

Courtney Harper, Ph.D.  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use Form

510(k) Number (if known): K110648

Device Name: Nova Stat Profile pHox Ultra Analyzer System

### Indications for Use:

The Nova Stat Profile pHox Ultra Analyzer with CO-Oximeter is intended for *in vitro* diagnostic use by health care professionals and for point-of-care usage in the quantitative determination of pH, PCO<sub>2</sub>, PO<sub>2</sub>, SO<sub>2</sub>%, Hematocrit (Hct), total Hemoglobin (tHb), Oxyhemoglobin (O<sub>2</sub>Hb), Carboxyhemoglobin (COHb), Methemoglobin (MetHb), Deoxyhemoglobin (HHb), and total bilirubin (tBil) in heparinized whole blood; Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>++</sup>, Mg<sup>++</sup>, Glucose (Glu), Lactate (Lac), BUN (Urea), and Creatinine (Creat) in heparinized whole blood, serum, or plasma. Total Bilirubin (tBil) was not evaluated on neonatal samples.

The Nova Stat Profile pHox Ultra Analyzer without CO-Oximeter is intended for *in vitro* diagnostic use by health care professionals and/or point-of-care usage in the quantitative determination of pH, PCO<sub>2</sub>, PO<sub>2</sub>, SO<sub>2</sub>%, Hematocrit (Hct), Hemoglobin (Hb) in heparinized whole blood; Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>++</sup>, Mg<sup>++</sup>, Glucose (Glu), Lactate (Lac), BUN (Urea), and Creatinine (Creat) in heparinized whole blood, serum, or plasma.

The intended use of the Nova STP pHox Ultra Calibrator Cartridge is for the quantitative determination of pH, PCO<sub>2</sub>, PO<sub>2</sub>, SO<sub>2</sub>%, Hematocrit (Hct), Hemoglobin (Hb) in heparinized whole blood; Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>++</sup>, Mg<sup>++</sup>, Glucose (Glu), Lactate (Lac), BUN (Urea), and Creatinine (Creat) in heparinized whole blood, serum, or plasma.

Prescription Use   X  

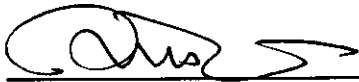
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

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PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K110648



## Indications for Use Form

510(k) Number (if known): K110648

Device Name: Nova Stat Profile pHox Ultra Analyzer System

### Indications for Use:

The intended use of the Nova Stat Profile pHox Ultra Analyzer CO-Oximeter Calibrator Cartridge with Bilirubin and Deproteinizing Solution is for the quantitative determination of total Hemoglobin (tHb), Oxyhemoglobin (O2Hb), Carboxyhemoglobin (COHb), Methemoglobin (MetHb), Deoxyhemoglobin (HHb), and total bilirubin (tBil) in human blood using the Nova Stat Profile pHox Ultra Analyzer System with CO-Oximeter.

Nova Stat Profile pHox Ultra Analyzer CO-Oximeter Controls and Autocartridge QC are intended for *in vitro* diagnostic use by healthcare professionals for monitoring the performance of Nova Stat Profile pHox Ultra Analyzer.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use             
(21 CFR 801 Subpart C)

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PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



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Division Sign-Off  
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